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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,251	08/03/2001	Thomas A. Steitz	044574-5070-1	2247

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Testa, Hurwitz & Thibault, LLP
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EXAMINER

MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/922,251	Applicant(s) STEITZ ET AL.	
	Examiner Channing S Mahatan	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 76 and 79-105 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 76 and 79-105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11 Sheets</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments filed 04 November 2003 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 76 and 79-105. Claims 1-74, 77, 78, and 106 have been cancelled.

INFORMATION DISCLOSURE STATEMENT

The previous office action mailed 01 July 2003 indicated several cited references were not considered because these references could not be located either within the instant application or central facility. Applicants' have provided copies of the missing references and attached are the 'Information Disclosure Statements'. Additionally, the reference to EP International Search Report (C107; Application No. 02255442.2) was lined through because the said reference is not publicly available.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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NEW MATTER

Claims 76 and 79-105 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 76 and all claims dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph. The introduction of “identify a candidate molecule capable of having binding specificity for the ribofunctional locus” to claim 76 is considered new matter.

Applicants assert support for the amendment to claim 76 can be found in the section relating to “Rational Drug Design” starting at page 76, and more specifically in the section entitled “Identification of Candidate Molecules” starting on page 103.

This is incorrect since there did not appear to be any disclosure or contemplation of “identifying a candidate molecule capable of having binding specificity for the ribofunctional locus” throughout the specification. For instance, the “more specifically” section discusses the general identification (i.e. two of factors) of designing molecules that bind to the functional activity of the ribosomes or ribosomal subunits, wherein the section states:

“The design of molecules that bind to or inhibit the functional activity of ribosomes or ribosomal subunits according to this invention generally involves consideration of two factors. First, the molecule must be capable of physically and structurally associating with the large ribosomal unit. Non-covalent molecular interactions important in the association of ribosomes and ribosomal subunits with the molecule, include hydrogen bonding, van der Waals and hydrophobic interactions. Second, the molecule must be able to assume a conformation that allows it to

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associate with the ribosomes or ribosomal subunits, more preferably with the large ribosomal subunits, and even more preferably with the 50S ribosomal subunit. Although certain portions of the molecule may not directly participate in this association with a ribosome or ribosomal subunits those portions may still influence the overall conformation of the molecule.” (page 103, lines 19-28).

and does not recite “binding specificity” nor provides support for “binding specificity” nor for “binding specificity for the ribofunctional locus”. One of skill in the art at the time of the invention would not have known and understood what is considered “capable of having binding specificity for the ribofunctional locus” in the absence of a definition within the specification (refer to below 35 U.S.C. 112 2nd Paragraph Rejection).

Therefore, the introduction of “identify a candidate molecule capable of having binding specificity for the ribofunctional locus” to claim 76 is considered NEW MATTER.

Claim 80 and all claims dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph. The introduction of the additional step “repeating step (b) to identify a modified molecule” to claim 80 is considered new matter.

Applicants assert support for the above amendment to claim 80 is found in the specification (first full paragraph of page 77) which recites the following with regard to “repeating step (b) to identify a modified molecule”:

“In summary, the tools and methodologies provided by the present invention may be used to identify and/or design molecules which bind and/or interact in desirable ways with ribosomes and ribosomal subunits. Basically, the procedures utilize an iterative process whereby the molecules are synthesized, tested and characterized. New molecules can be designed based on the information gained in the testing and characterization of the initial molecules and then such may

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be repeated as many times as necessary to obtain molecules with desirable binding properties and/or biological activities.” (page 77, lines 5-13)

However, the specification does not provide support for “repeating step (b) to identify a modified molecule”. It is acknowledged the above section does provide support for an “iterative process whereby the molecules are synthesized, tested and characterized” but fails to make any connection to identify modified molecules. Further, step (b) (via claim 76) does not perform the task of modifying a molecule nor disclose criteria/parameters that are indicative of a modified molecule. Therefore, the introduction of “repeating step (b) to identify a modified molecule” is considered NEW MATTER.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 76 and 79-105 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 76 and all claims dependent therefrom recite the limitation “capable of having binding specificity for the ribofunctional locus” which is vague and indefinite. It is unclear what Applicants’ intend such language to encompass, wherein the specification does not provide any indication for “binding specificity for the ribofunctional locus”. Clarification of the metes and bounds, via clearer claim language, is requested.

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Claim 83 is confusing wherein the instant claim recites "the additional step of producing the modified molecule", however, claim 81 (which claim 83 via 82 depends from) recites the same step. Clarification of the metes and bounds, via clearer claim language, is requested.

OBJECTION TO DISCLOSURE

The disclosure is objected to because of the following informalities:

The disclosure is objected to because of a typographical error on page 140, line 13) wherein "Disk No. 2 of 2:" should be corrected to "Disk No. 2 of 3:".

Appropriate Correction Is Requested.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *January 23, 2004*
Examiner Initials: *CSM*

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
AU/631